

Notice of Allowability

Application No.

10/647,818

Examiner

David J. Blanchard

Applicant(s)

YOUNG ET AL.

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 07 August 2006 and 12 October 2006.
2. ☒ The allowed claim(s) is/are 23-26, 28-30, 33-37, 39-40 and 44-45 (renumbered as claims 1-16).
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |


SHEELA H. HITE
PRIMARY EXAMINER

EXAMINER'S COMMENT

Election/Restrictions

1. Upon further consideration the restriction requirement among Groups I and II as set forth in the restriction requirement mailed 30 January 2006 is hereby withdrawn and claims directed to the inventions of Groups I and II are fully examined for patentability under 37 CFR 1.104. It is noted that the restriction requirement pertaining to the invention of Group III in the restriction requirement mailed 30 January 2006 is maintained.

In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicants are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ferris H. Lander on 12 October 2006.

The claims have been amended as follows:

In claim 23 (renumbered as claim 1), the phrase "a CD44 antigenic moiety" has been deleted and replaced with the term "CD44".

In claim 23 (renumbered as claim 1), the phrase "which antigenic moiety" has been deleted and replaced with the term "which".

In claim 23 (renumbered as claim 1), the phrase "expressed CD44 antigenic moiety" has been deleted and replaced with the term "CD44".

In claim 28 (renumbered as claim 5), the phrase "obtained from a tumor originating in a tissue" has been deleted.

In claim 28 (renumbered as claim 5), the term "tissue" has been deleted.

In claim 29 (renumbered as claim 6), in each of lines 2-3 and 16-17 the phrase "a CD44 antigenic moiety which specifically binds to" has been deleted and replaced with the phrase "CD44 which is specifically recognized by".

In claim 30 (renumbered as claim 7), the phrase "obtained from a tumor originating in a tissue" has been deleted.

In claim 33 (renumbered as claim 8), the phrase "by treating a breast tumor" has been deleted.

In claim 33 (renumbered as claim 8), the term "isolated" has been inserted following the term "said mammal said".

In claim 33 (renumbered as claim 8), the term "isolated" has been inserted following the term "produced from said".

In claim 39 (renumbered as claim 13) the term "administered" has been inserted following the term "the antibody".

In claim 40 (renumbered as claim 14) the term "23" has been deleted and replaced with the term "33".

In claim 40 (renumbered as claim 14) the term "administered" has been inserted following the term "the antibody".

In claim 44 (renumbered as claim 15), the phrase "the antibody is" has been deleted and replaced with the phrase "said cell sample is contacted with".

In claim 45 (renumbered as claim 16), the phrase "the antibody is" has been deleted and replaced with the phrase "said cell sample is contacted with".

REASONS FOR ALLOWANCE

3. The following is an examiner's statement of reasons for allowance:

The prior art does not teach or fairly suggest the monoclonal antibody produced by the hybridoma deposited with the ATCC as Accession Number PTA-4621. It is noted that the claimed invention relies on a biological material (i.e., the monoclonal antibody produced by the hybridoma deposited with the ATCC as Accession Number PTA-4621) requiring a biological deposit to satisfy the statutory requirements for patentability under 35 U.S.C. 112. However, Applicant has met all of the biological requirements for the hybridoma deposited with the ATCC as Accession Number PTA-4621 and has provided

all of the necessary assurances, i.e., "all restrictions imposed on the availability to the public of the deposited materials will be irrevocably removed upon the granting of a patent" (pg 39 of the specification). For these reasons the present claims are in condition for allowance.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic
Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827



SHEELA HUFF
PRIMARY EXAMINER